K111444

510(k) Summary

JUN 2 2 2011

Submitted by:
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581
Phone: (305) 269-6386
Fax: (305) 269-6441

Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared: May 17, 2011

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Universal and Troch Entry Femoral Nailing Systems Line Extension	Intramedullary fixation rod and accessories

Name of Predicate Devices

The device is substantially equivalent to the currently marketed DePuy Universal and Troch Entry Femoral Nailing Systems, K033329 and the Hip Fracture Nail, K100238.

Classification

Class II, 21 CFR 888.3020, product code HSB

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

Device Description

The Universal and Troch Entry Femoral Nailing Systems Line Extension offers an additional 5mm distal screw, 20-80mm. The system consists of Universal and Troch Entry nails for femoral fracture fixation. The titanium nails range in diameter from 9 – 15mm and lengths of 280 – 500mm.

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Indications for Use	The Universal and Troch Entry Femoral Nailing Systems Line Extension is intended to treat proximal, middle and distal third fractures, severely comminuted shaft fractures extending beyond the isthmus, spiral, long oblique and segmental fractures, non-unions and malunions, lengthening of the bone, fractures with bone loss, bi-lateral fractures, pseudoarthrosis of the femoral shaft, supracondylar fractures, subtrochanteric fractures, with or without involvement of lesser trochanter, subtrochanteric / intertrochanteric combination fractures, ipsilateral femoral shaft and neck fractures, stable and unstable proximal fractures of the femur, including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, pertrochanteric features associated with shaft fractures, pathologic fractures in osteoporotic bone of the trohchanteric and diaphyseal areas, proximal or distal non-unions and malunions, leg length discrepancies secondary to femoral inequality, femur reconstruction following tumor resection, stable femoral fractures without necessity for interlocking, long subtrochanteric fractures, and revision procedures involving the replacement of implanted hardware. In addition to the above indications, the Universal NAIL, when used in the retrograde mode, is also indicated for treatment of femoral shaft fractures in obese or multiple trauma patients and supracondylar fractures, including those with severe, extra-articular comminution and/or intra-articular involvement, osteoporosis, non-unions, malunions, pathologic fractures, and those proximal to total knee prosthesis..
Technological Characteristics	The technological characteristics of the Universal and Troch Entry Femoral Nailing Systems Line Extension are similar to the predicate devices in both design and material. The systems are manufactured from titanium alloy. Dimensional characteristics are similar among the systems and identical to the screws in the Hip Fracture Nail System.
Summary of Substantial Equivalence	The Universal and Troch Entry Femoral Nailing System Line Extension is substantially equivalent to the predicate devices as confirmed through bench testing. Dimensional analysis, torque and bend testing demonstrated that the 5mm screws performed equivalently to the predicate devices, successfully meeting the pre-determined acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Project Manager, Regulatory Affairs
700 Orthoaedic Drive
Warsaw, IN 46581

JUN 2 2 2011

Re: K111444
Trade/Device Name: Universal and Troch Entry Femoral Nail Systems Line Extension
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 17, 2011
Received: May 24, 2011

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K111444

Device Name: **Universal and Troch Entry Femoral Nail Systems Line Extension**

Indications For Use:

Intended to treat proximal, middle and distal third fractures, severely comminuted shaft fractures extending beyond the isthmus, spiral, long oblique and segmental fractures, non-unions and malunions, lengthening of the bone, fractures with bone loss, bi-lateral fractures, pseudoarthrosis of the femoral shaft, supracondylar fractures, subtrochanteric fractures, with or without involvement of lesser trochanter, subtrochanteric / intertrochanteric combination fractures, ipsilateral femoral shaft and neck fractures, stable and unstable proximal fractures of the femur, including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, pertrochanteric features associated with shaft fractures, pathologic fractures in osteoporotic bone of the trohchanteric and diaphyseal areas, proximal or distal non-unions and malunions, leg length discrepancies secondary to femoral inequality, femur reconstruction following tumor resection, stable femoral fractures without necessity for interlocking, long subtrochanteric fractures, and revision procedures involving the replacement of implanted hardware. In addition to the above indications, the Universal Nail, when used in the retrograde mode, is also indicated for treatment of femoral shaft fractures in obese or multiple trauma patients and supracondylar fractures, including those with severe, extra-articular comminution and/or intra-articular involvement, osteoporosis, non-unions, malunions, pathologic fractures, and those proximal to total knee prosthesis.

Prescription Use X AND/OR Over-the-Counter_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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